PATENT COOPERATION TREATY REC'D 25 JUL 2005

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| | SEARCHING AUTHOR | ITV |
| NTERNATIONAL | SEARCHING ACTION | |

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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing

(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference see form PCT/ISA/220

FOR FURTHER ACTION See paragraph 2 below

International application No.

International filing date (day/month/year)

PCT/GB2005/001612

27.04.2005

Priority date (day/month/year) 27.04.2004

International Patent Classification (IPC) or both national classification and IPC

A61M3/02

Applicant

SMITH & NEPHEW, PLC

- This opinion contains indications relating to the following items: 1.
 - Basis of the opinion ☑ Box No. I
 - Box No. Ⅱ Priority
 - Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☑ Box No. III
 - Lack of unity of invention ☐ Box No. IV
 - Reasoned statement under Rule 43bis 1(a)(i) with regard to novelty, inventive step or industrial Box No. V
 - applicability; citations and explanations supporting such statement
 - Certain documents cited ☐ Box No. VI
 - Certain defects in the international application Box No. VII
 - Box No. VIII Certain observations on the international application

FURTHER ACTION 2.

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

For further details, see notes to Form PCT/ISA/220. 3.

Name and mailing address of the ISA:

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Authorized Officer

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/GB2005/001612

| | | | · | | | |
|----------------------|------------|-------------|----------------|--|--|--|
| | Во | x N | o. I | Basis of the opinion | | |
| 1. | Wit the | h re lan | garo guaç | I to the language , this opinion has been established on the basis of the international application in ge in which it was filed, unless otherwise indicated under this item. | | |
| | | lar | ngua | pinion has been established on the basis of a translation from the original language into the following ge , which is the language of a translation furnished for the purposes of international search Rules 12.3 and 23.1(b)). | | |
| 2. | Wit | th re | egard sary | to any nucleotide and/or amino acid sequence disclosed in the international application and to the claimed invention, this opinion has been established on the basis of: | | |
| a. type of material: | | | | | | |
| | | | a s | equence listing | | |
| | | | tab | le(s) related to the sequence listing | | |
| | b. 1 | form | nat o | f material: | | |
| | | | in v | vritten format | | |
| | | | in o | computer readable form | | |
| | c. 1 | time | of f | iling/furnishing: | | |
| | | | cor | ntained in the international application as filed. | | |
| | | | file | d together with the international application in computer readable form. | | |
| | | | fur | nished subsequently to this Authority for the purposes of search. | | |
| 3. | | h: C0 | as be opies | lition, in the case that more than one version or copy of a sequence listing and/or table relating thereto een filed or furnished, the required statements that the information in the subsequent or additional is is identical to that in the application as filed or does not go beyond the application as filed, as priate, were furnished. | | |
| 4. | Ad | lditio | onal | comments: | | |
| | | | | | | |
| _ | Вс | Λ xc | lo. II | Priority | | |
| 1. | × | d re | oes eauir | alidity of the priority claim has not been considered because the International Searching Authority not have in its possession a copy of the earlier application whose priority has been claimed or, where ed, a translation of that earlier application. This opinion has nevertheless been established on the option that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date. | | |
| 2. | | h | as b | opinion has been established as if no priority had been claimed due to the fact that the priority claim een found invalid (Rules 43 <i>bis.</i> 1 and 64.1). Thus for the purposes of this opinion, the international date indicated above is considered to be the relevant date. | | |
| 3. | . Ac | diti | onal | observations, if necessary: | | |

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/GB2005/001612

| | _ | | | | | | |
|---|---|-------|-----------------------------------|--|--|--|--|
| Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | | | |
| The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of: | | | | | | | |
| | the entire international application, | | | | | | |
| × | claims Nos. 14 | | | | | | |
| because: | | | | | | | |
| | the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify): | | | | | | |
| | the description, claims or drawings <i>(indicate particular elements below)</i> or said claims Nos. are so unclear that no meaningful opinion could be formed <i>(specify)</i> : | | | | | | |
| | the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed. | | | | | | |
| \boxtimes | no international search report has been established for the whole application or for said claims Nos. 14 | | | | | | |
| | the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that: | | | | | | |
| | the written form | | has not been furnished | | | | |
| | • | | does not comply with the standard | | | | |
| | the computer readable form | | has not been furnished | | | | |
| | | | does not comply with the standard | | | | |
| | the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions. | | | | | | |
| 153 | Soo congrate cheet for further | detai | ile | | | | |

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/GB2005/001612

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

No: Claims

1-13

Inventive step (IS)

Yes: Claims

Claims

No:

1-13

Industrial applicability (IA)

Yes: Claims

.1-13

No: Claims

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 14 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT: a method of treating wounds to promote wound healing. For said claim no international search report has been established and, consequently, no examination will be carried out with respect to the novelty, inventive step and industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: US 2002/161346 A1 (LOCKWOOD JEFFREY S ET AL) 31 October 2002 (2002-10-31)

D2: US 2003/021775 A1 (FREEMAN AMIHAY) 30 January 2003 (2003-01-30)

1. The present application does not meet the criteria of Article 33(1) PCT, because **the subject-matter of claim 1 is not new** in the sense of Article 33(2) PCT.

Document D1 discloses an apparatus for cleansing wounds, comprising:

- I) a fluid flow path, comprising a conformable wound dressing, having a backing layer which is capable of forming a relatively fluid-tight seal over a wound, and
- an inlet pipe (652) for connection to a fluid supply (14), which passes under the wound-facing face (656), and
- an outlet pipe (23) for connection to a fluid offtake tube (13), which passes through the wound-facing (652) face forming a relatively fluid-tight seal over the wound (paragraph [0018]);
- ii) a fluid reservoir (14) connected by a fluid supply tube (see fig. 36) to the inlet pipe (652):
- iii) a device for moving fluid through the wound dressing (paragraph [0086]);
- iv) means for supplying physiologically active agents to the wound (paragraph

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

International application No.

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[0071]); and

v) means for providing simultaneous aspiration and irrigation of the wound (paragraph [0116]),

such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube while fluid is aspirated by a device through the fluid offtake tube (see fig. 36).

All features of claim 1 are also known from document D2.

 Dependent claims 2-13 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty, as all said features are either already known from documents D1 or D2, or obvious to those skilled in the art.

Re Item VII

Certain defects in the international application

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Re Item VIII

Certain observations on the international application

Claims 1 and 7 are not clear (Article 6 PCT) for the following reasons:

- I) claim 1 defines "a device for moving fluid through the wound dressing", what leaves the reader in doubt if the fluid is moved through a tubing which passes through the dressing or through the dressing itself (which could be e.g. fluid permeable);
- ii) claim 7 defines that the means for providing aspiration and irrigation **often** comprises a first device, a second device, etc., therefore leaving the reader in doubt as to the scope of the claimed subject matter.